K072950

CYGNUS

Technology as Passion

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AUG 22 2008

510(k) Summary
[As required by 21 CFR 807.92(c)]

1. Submitter Information:

Name:	Cygnus LLC
Address:	510 East 41st Street, Paterson, NJ 07504
Telephone:	973-523-0668
Fax:	973-523-0375
Email:	info@cygnusnj.com
Contact Person:	Narcis Naydenov
Date Prepared:	September 26, 2007

2. Device:

Proprietary Name:	Cygnus 12 Lead/TTM ECG Module
Common Name:	Analyzer, Pacemaker Generator Function, Indirect
Classification Name:	Class II (21 CFR 870.3640, Product code KRE)

3. Description:

Cygnus 12 Lead/TTM ECG module is a fully functional ECG and Pacemaker monitoring system that is powered through a PC USB (Universal Serial Bus) port.

Four general parts could be distinguished in the Cygnus 12 Lead/TTM ECG module:

- An analog front end.

- Digital Signal Processing – USB Interface Unit.
- TTM Interface for analog phone lines.
- TTM Interface for digital phones.

The module measures the 12 standard ECG leads on the isolated input, and is capable of acting as an ECG Receiving Station over the phone line for ECG and pacemaker encoded signal with Frequency Modulation (FM).

4. Intended Use:

- The device is for prescription use only.
- The device is intended to be used in a clinic or hospital.
- The device is intended for use by the physician (or his/her representative), not by the patient, although one intended use is to record the patient's 12-lead ECG.
- The device is intended for use as a :
  Fully functional ECG/heart rate monitoring system for clinical use.
  Pacemaker Detection and measurement.
  A TTM (trans-telephonic) Receiving Station.
- In TTM mode, the device is intended for use with landline analog and digital PBX telephone systems only. It is not intended to be used with wireless networks.

5. Substantially equivalent devices:

Cygnus LLC considers the legally marketed PACEART CPTS-86/12 (K915632) cardiac receiving station to be substantially equivalent to Cygnus 12 Lead/TTM ECG Module, with a number of features shared.

6. Summary of testing:

The device was tested in accordance with applicable sections of AAMI/ANSI EC 11: 1991, *Diagnostic Electrocardiographic D*evices and AAMI/ANSI EC 38: 1998, *Ambulatory Electrocardiographs*.

7. Conclusion:

Based on the information presented in this application, and namely the functional similarities with K915632, Cygnus LLC considers the Cygnus 12 Lead/TTM ECG Module to be substantially equivalent to a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2008

Cygnus, LLC
c/o Mr. Narcis Naydenov
Member of Board
510 East 41st Street
Paterson, NJ 07504

Re: K072950
Trade/Device Name: Cygnus 12 Lead/TTM ECG Module
Regulation Number: 21 CFR 870.3640
Regulation Name: Indirect pacemaker generator function analyzer
Regulatory Class: Class II (Two)
Product Code: KRE
Dated: August 18, 2008
Received: August 19, 2008

Dear Mr. Naydenov:

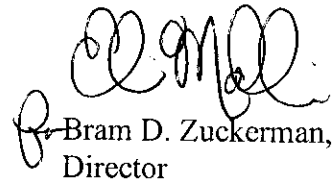
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1/1

Indications for Use Statement

(k) Number (if known):K072950

Device Name: Cygnus 12 Lead/TTM ECG module

Indication for Use:

- The device is for prescription use only.
- The device is intended to be used in a clinic or hospital.
- The device is intended for use by the physician (or his/her representative), not by the patient, although one intended use is to record the patient's 12-lead ECG.
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072950